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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,048	07/30/2001	Timothy J. O'Brien	D6223CIP/A/D/CIP	4713

7590 12/13/2002

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1642	7

DATE MAILED: 12/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/919,048	O'BRIEN ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *6* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet* .

Continuation of Attachment(s) 6). Other: Restriction Election Facsimile Transmission.

Election/Restrictions

1. Please note that the Examiner of record has changed. Contact information is provided at the close of the action.

2. Applicants' response to the previous Examiner's election/restrictions requirement is of record in Paper number 5, received October 1, 2002. However, upon reconsideration the current Examiner has set forth the following new election/restrictions requirement.

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to methods for detecting malignant hyperplasia by assaying for mRNAs for hepsin, classified in class 435, subclass 6.

II. Claims 7, 29 and 30, drawn to antisense therapeutic methods, classified in class 514, subclass 44.

III. Claims 8-13, drawn to methods of inhibiting expression using an antibody, classified in class 424, subclass 138.1.

IV. Claims 10-13, drawn to methods of inhibiting expression using a ligand, classified in class 514, subclass 2.

V. Claims 14-17, drawn to a method of vaccinating against hepsin, classified in class 424, subclass 184.1.

VI. Claims 18-23, drawn to a method of producing immune-activated cells, classified in class 435, subclass 325.

VII. Claims 24-26, drawn to immunogenic compositions, classified in class 530, subclass 300.

VIII. Claims 27 and 28, drawn to oligonucleotides, classified in class 536, subclass 23.2.

IX. Claim 31, drawn to a method of screening for inhibitors, classified in class 435, subclass 4.

4. The inventions are distinct, each from the other because of the following reasons:

Inventions I-VI and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to distinct methods, which require performing different method steps and involve the use of different reagents. In particular, the methods of Invention I require the use of primers and probes and involve performing PCR or nucleic acid hybridization assays to detect the presence of mRNA as indicative of he occurrence of malignant hyperplasia. Invention II requires the use of a vector comprising antisense oligonucleotides and treatment of an individual or a cell in order to achieve the objective of inhibiting gene expression. Invention III requires the use of an antibody and treatment of an individual or cell with an antibody in order to achieve the objective of inhibiting protein activity. Invention IV requires the use of a ligand and treatment of an individual or cell with a ligand in order to achieve the objection of inhibiting protein activity. Invention V requires the use of a vaccine

comprising a protein and administration of a vaccine to an individual to achieve the objective of vaccinating an individual. Invention VI requires the use of B, T or dendritic cells in order to produce immune-activated cells. Invention IX requires the use of a test compound and hepsin protein and assaying for protease activating in order to achieve the objective of identifying compounds that inhibit hepsin activity. Inventions I-VI and IX are novel and unobvious over each other.

Inventions I and VII and Inventions II and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different functions because the methods of Inventions I and II do not require the proteins of Invention VII.

Inventions I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the oligonucleotides of VIII can be used in a materially different process such as for synthesizing polypeptides or for therapeutic purposes.

Inventions III-VI, IX and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP §

808.01). In the instant case the different inventions are not disclosed as capable of use together and have different functions because the methods of inventions III-VI and IX do not require the oligonucleotides of inventions VIII.

Inventions III, IV, IX and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the proteins of invention VII can be used in a materially different process such as for generating antibodies or for diagnostic purposes.

Inventions V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the proteins of Invention VII can be used in a materially different process such as for diagnostic purposes or for screening for protease inhibitors.

Inventions VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different functions and effects. In particular, the proteins of Invention VII are

composed of amino acids whereas the oligonucleotides of Invention VIII are composed of nucleotides. Proteins and nucleic acids have distinct structural and physiochemical properties and are utilized in distinct methodologies, such that proteins may be utilized in ligand binding assays and oligonucleotides may be utilized in nucleic acid hybridization assays. The oligonucleotides of Invention VIII are not required to obtain the proteins of Invention VII because the proteins may be chemically synthesized or isolated from natural sources.

5. ***Sequence Election Requirement Applicable to Groups III and V-VII***

In addition, Inventions III and V-VII detailed above read on patentably distinct inventions drawn to multiple SEQ ID numbers. The sequences are patentably distinct because they are structurally and functionally unrelated sequences, and a further restriction is applied to each invention. **In response to the restriction requirement, Applicants must further elect a single peptide selected form the group consisting of SEQ ID NO: 28-31, 88, 89, 108, 109, 128, 129 and 148-154.**

It is noted that nucleotide sequences encoding different proteins and/or having distinct nucleotide sequences are structurally distinct chemical compounds and re unrelated to one another. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121 and 372. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

ALANA HARRIS
PATENT EXAMINER

Alana M. Harris, Ph.D.
December 12, 2002